

## **FOR IMMEDIATE RELEASE**

### **Rising Clinical Trial Complexity Continues to Vex Drug Developers, According to Tufts Center for the Study of Drug Development**

BOSTON – May 5, 2010 – Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs, according to a study recently completed by the Tufts Center for the Study of Drug Development.

The study found that the median number of procedures per clinical trial increased by 49% between 2000-03 and 2004-07, while the total effort required to complete those procedures grew by 54%.

The new study updates an analysis conducted by Tufts CSDD two years ago, which provided the first quantitative assessment of the impact of protocol design on clinical trial performance.

“More complex and burdensome protocols are extending study cycle times, increasing costs, and challenging patient recruitment and retention,” said Tufts CSDD Senior Research Fellow Ken Getz, who conducted the study. “Wide observed differences in complexity and execution burden by phase and therapeutic area indicate that pharmaceutical and biotechnology companies can target their efforts to improve protocol design and improve clinical trial operating performance.”

According to Getz, the rise in the number of eligibility criteria used to screen volunteers has contributed to a decline in volunteers enrolling in clinical trials. And once volunteers enroll, he said, the larger number of procedures per protocol is dissuading study volunteers from staying in trials through to completion.

The new analysis, reported in the May/June *Tufts CSDD Impact Report*, released today, also found that:

- \* Wide variability exists in complexity and execution burden per protocol between therapeutic areas and clinical study phases, indicating opportunities to streamline design.
- \* Between 2002 and 2007, protocols targeting diseases in oncology, immunology, and the central nervous system saw the most rapid growth in the total number of procedures and in the burden to execute those procedures.
- \* Overall growth in complexity and execution burden grew at the slowest rate for protocols in Phase III studies, as companies, looking to contain costs, gathered more data in early phases of clinical research.

#### **About the Tufts Center for the Study of Drug Development**

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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